

REMARKS

Formal Matters

Claims 2, 11, 17, 19, 43 and 71-93 are pending after entry of the amendments set forth herein.

Claims 2, 11, 17, 19, 43 and 71-92 were examined. Claims 2, 11, 17, 19, 43 and 71-92 were rejected.

Applicants respectfully request reconsideration of the application in view of the amendments and remarks made herein.

No new matter has been added.

The Office Action

The Telephone Interview

During the telephone interview of March 5, 2010, Applicants' representative noted to Examiner Woo that the Advisory Action of February 18, 2010 made no mention of the newly submitted claim 93. Examiner Woo indicated that a Supplemental Advisory Action would be issued so as to address claim 93. To date, Applicants have not received a supplemental Advisory Action nor has one been posted on PAIR.

Regarding the Examiner's rejection of claims 2, 11, 17, 19, 43, 71-87 and 90-91 under 35 U.S.C. Section 112, first paragraph, the Examiner agreed that changing the language "insufficient material memory" to "little material memory in that once deformed from one shape to another, it will not move back into the first shape from the second—would overcome this ground of rejection.

This account is believed to be a complete and accurate summary of the interview as required by 37 C.F.R. § 1.133. If the Examiner believes that this summary is inaccurate or incomplete, Applicants respectfully request that the Examiner point out any deficiencies in her next communication so that Applicants can amend or supplement the interview summary.

Office Action Summary

Claims Rejected Under 35 U.S.C. Section 112, First Paragraph

In the Official Action of November 23, 2009, claims 2, 11, 17, 19, 43, 71-87 and 90-91 were rejected under 35 U.S.C. Section 112, first paragraph, as failing to comply with the written description requirement.

The Examiner asserted that the originally file description does not describe “said deformable material has insufficient material memory”. The Examiner asserted that “The specification simply states on page 31 that ‘the retention means has little material memory’.”

In the Advisory Action dated February 18, 2010, the Examiner asserted that “insufficient material memory” could mean a lot, but not enough. Although Applicants do not agree with this distinction, as Applicants would not characterize a material having insufficient memory to return the material to its original shape, once deformed, as having “a lot” of material memory. Nevertheless, in order to advance the prosecution of the present application, Applicants have amended claims 1, 43 and 87 above to recite that the material has little material memory such that once deformed from one shape into another, it will not move back into said one shape from said another shape. Applicants respectfully submit that one of ordinary skill in the art would readily understand this property of a malleable material.

In view of the above amendments and remarks, the Examiner is respectfully requested to reconsider and withdraw the rejection of claims 2, 11, 17, 19, 43, 71-87 and 90-91 under 35 U.S.C. Section 112, first paragraph, as failing to comply with the written description requirement, as being improper.

Claims Rejected Under 35 U.S.C. Section 102(b) (Baker et al.)

Claims 2, 11, 17, 19, 71-72, 74-77, 79, 83-85 and 87-92 were rejected under 35 U.S.C. Section 102(b) as being anticipated by Baker et al., U.S. Patent No. 6,221,102.

The Examiner asserted that Baker et al. discloses an anastomotic apparatus (“capable of being used for as an anastomotic apparatus”) for placing an inside edge surface of an incision in a first vessel in healing contact with an inside edge surface of an incision in a second vessel to establish flow between the vessels.

Applicants respectfully traverse. Baker et al. discloses an intraluminal grafting system, see the title and the abstract. As such, Baker et al. describes a graft that is comprised of a tubular body configured to be secured to a blood vessel by a self expanding attachment system, see the abstract. There is no disclosure or suggestion by Baker et al. of using the graft of Baker et al. to join incision edge surfaces of first and second vessels along incisions thereof. Accordingly, it is respectfully submitted that the Examiner's assertions are pure speculation and unsupported by the disclosure of Baker et al.

It is respectfully submitted that even if one were to attempt to perform an anastomosis using the graft of Baker et al. (although Baker et al. certainly does not suggest this as the attempt would result in failure), there is no structure provided in the graft that would ensure that the inside edge surfaces along incisions of first and second vessels would be held in healing contact with one another, as the hook features 151 of Baker et al. are spaced too far apart from each other (i.e., at opposite ends of the tubular graft) and would not function to ensure that the incised edges would remain in healing contact.

The Examiner further asserted that Baker et al. discloses a sinuous, stiffening framework 138 having a plurality of malleable sections (Fig. 11) formed of a deformable material which causes the framework to remain in a second configuration after being deformed from a first configuration, even after cessation of application of deformation force used to deform said framework into said second configuration. The Examiner reasoned that the hooks 151 attach to the tissue, so that when the balloon is removed, the framework does not return to the first configuration because the framework is now attached to the tissue.

Element 131 shown in Fig. 11 refers to a spring means. The helical coil springs 136 placed at the nodes or apices of the vees 132 of the spring means 131 serve to facilitate compression of the graft when it is desired to place the same within the capsule 36 of Baker et al., see column 11, lines 48-51.

The compression of the graft is accomplished by deformation of the coil springs 136 within their elastic limits. The natural spring forces of the helical coil springs 136 provided in the apices of the vees serves to expand the graft to its expanded position as soon as the graft is free of the capsule 36 (Fig. 1), see column 11, lines 59-62.

It is respectfully submitted that the Examiner has misinterpreted the Baker et al. reference. The Examiner indicated that "the delivery balloon is the force that deforms the framework". Applicants respectfully traverse. Contrary to the Examiner's assertion, Baker et al. discloses that the framework is deformed (elastically deformed) to compress it to a smaller size to place it within the capsule 36, see column 11, lines 48-51. Baker et al. further discloses that the framework self expands (i.e., due to the material memory of the spring means 131) to spring into engagement with the vessel wall 166 as soon as

the proximal extremity of the graft has cleared the distal extremity of the capsule, see column 14, lines 12-17.

The balloon 64 is expanded to urge the hook-like elements 151 outwardly to firmly seat within the vessel wall 166, not to deform the struts 138, contrary to the Examiner's interpretation, see column 14, lines 28-32. Further, Baker et al. discloses that the graft can be implanted without the use of the inflatable balloon, as the spring forces provided by the helical coil springs are sufficient to force the hook-like elements into the wall of the vessel to inhibit migration of the graft, see column 16, lines 15-25.

The Examiner asserted that element 138 has insufficient material memory to move back to a first shape once deformed to a second shape. Applicant respectfully submit that Baker et al. does not appear to support the Examiner's assertion. To the contrary, Baker et al. discloses that the struts 137 and 138 are brought closer together when the spring means 131 is elastically deformed. Then, upon release of the deformation forces (i.e., by pushing the graft out of the capsule, the struts 137 and 138 return to their original configuration (spaced further apart) due to the material memory of the spring means 131.

The Examiner further asserted that each malleable section comprises a curved apex 133. If the Examiner considers the "malleable section" to include an apex 133, then it is respectfully submitted that the Examiner cannot also define the "malleable section" as strut 138, but must define the "malleable section" as at least strut 138, apex 133 and strut 137. Further, Applicants note that Baker et al. disclose reference numeral 133 to be the apex of a helical coil 136 that creates a spring force, see column 11, lines 22-24. Baker et al. further discloses at column 11, lines 48-53:

The helical coil springs 136 placed at the nodes or apices 133 of the vees 132 of the spring means 131 serve to facilitate compression of the graft when it is desired to place the same within the capsule 36 as hereinafter described. The compression of the graft is accomplished by deformation of the coil springs 136 within their elastic limits.

It is respectfully submitted that the disclosure of Baker et al. does not support the Examiner's assertion that apices 133 are apices of malleable members, since Baker et al. discloses that the apices 133 are apices of coil springs.

The Examiner asserted that Baker et al. discloses a tool 64 having a head configured to be inserted into one of the vessels to attach said means for attaching to the vessel, said head located at a distal end portion of said tool, said head extending transversely to a longitudinal axis of said tool and having a bypass channel defined therethrough and extending transversely to the longitudinal axis, for maintaining blood flow through the vessel when said head is inserted into the vessel. The Examiner referred to Fig. 14 of Baker et al. in support of these assertions.

Applicants respectfully traverse. Fig. 14 shows that reference numeral 64 is a balloon. There does not appear to be any bypass channel through the balloon to allow blood to flow through it, contrary to the Examiner's assertion. The only channel shown is 69, which is a closed-ended tube used to stiffen the balloon 64, as well as to deflate it and inflate it. Further, tube 69 does not extend transversely to the longitudinal axis of the balloon 64, but rather is aligned with it.

Regarding claims 71-72, 74 and 87, the Examiner asserted that Baker et al. discloses a hemostatic medium in the form of a hole 122. Applicants do not understand how a hole can be considered to be a medium configured to stop the flow of blood. It is respectfully submitted that blood would flow through the hole 122 and therefore hole 122 would not function as a hemostatic medium.

The Examiner asserted that Fig. 14 of Baker et al. discloses an anvil as claimed. The Examiner did not specifically identify which portion of Fig. 14 is considered to disclose an anvil. Applicants have been unable to locate an anvil in Fig. 14, as Fig. 14 simply shows the spring means 131 mounted on a balloon 64 being delivered in a vessel. The Examiner is respectfully requested to identify, by specific reference numeral, what is considered to be the "anvil".

With regard to claim 79, the Examiner asserted that Baker et al. discloses first and second cuffs as claimed. The Examiner identified the first and second cuffs as being met by reference numerals 132 and 136 of Baker et al., respectively.

Applicants respectfully traverse. It is respectfully submitted that reference numeral 132 of Baker et al. refers to the V-shape of the spring means 131, and that the V-shape is formed, in part, by strut 138, see Fig. 11. Accordingly it is respectfully submitted that 132 and 138 cannot be reasonably considered to meet the recitations of first and second cuffs in the present claims, since 132 is not a structure at all, but rather a shape formed, in part, by the strut 138.

Regarding claim 85, the Examiner asserted that Baker et al. discloses docking extensions 151 configured to be manipulated to deform said stiffening framework into said second configuration. Reference numeral 151 of Baker et al. refers to a hook, not a docking extension. Further, the hooks 151 are not configured to be manipulated to deform the spring means 131 from a first configuration into a second configuration. The balloon 64 is used to expand the spring means 131, not the hooks 151.

On page 5, last bullet point of the Office Action dated April 21, 2009, the Examiner referred to the claimed malleable sections as being met by "one of 151". It is respectfully submitted that this is inconsistent with the Examiner's earlier indication that the malleable section has a curved apex 133, as the hook 151 does not have an apex 133. Accordingly, it is respectfully submitted that this interpretation is improper and should be withdrawn.

In view of the above amendments and remarks, the Examiner is respectfully requested to reconsider and withdraw the rejection of claims 2, 11, 17, 19, 71-72, 74-77, 79, 83-85 and 87-92 under 35 U.S.C. Section 102(b) as being anticipated by Baker et al., U.S. Patent No. 6,221,102, as being clearly inappropriate.

Claims Rejected Under 35 U.S.C. Section 102(b) (Schomacher)

Claim 43 was rejected under 35 U.S.C. Section 102(b) as being anticipated by Schomacher, U.S. Patent No. 4,233,981.

The Examiner asserted, inter alia, that Schomacher discloses shaping, by bending the mounting structure to define a desired flow area. The Examiner referred to column 4, lines 55-56 of Schomacher and indicated that this was interpreted as “inherently shaping by bending”.

Applicants respectfully traverse. Claim 43 recites, inter alia, that the mounting structure, when shaped by said bending, retains a shape resulting from said bending and has insufficient material memory to move back to shape assumed prior to said bending once bending forces have been removed. It is respectfully submitted that Schomacher provides an elastic material that follows the movement of the vessel, and that an elastic material will resume its shape when the bending force has been removed.

In view of the above remarks, the Examiner is respectfully requested to reconsider and withdraw the rejection of claim 43 under 35 U.S.C. Section 102(b) as being anticipated by Schomacher, U.S. Patent No. 4,233,981, as being clearly inappropriate.

Claims Rejected Under Nonstatutory Double Patenting

Claims 2, 11, 17, 19, 43 and 71-92 were rejected on the ground of nonstatutory obviousness-type double patenting, as being unpatentable over the claims of U.S. Patent Numbers 5868763, 6190397 and 6565581. The Examiner asserted that even though the conflicting claims are not identical, they are not patentably distinct from each other because the patent(s) listed above disclose all the limitations of the current invention.

Applicants respectfully traverse. It is respectfully submitted that the Examiner has not set forth a prima facie case of obviousness for the rejections over any of U.S. Patent Numbers 5868763, 6565581 and 6190397. It is respectfully submitted that merely because a prior patent discloses all of the limitations of a currently claimed invention, that this is insufficient basis for a double patenting

rejection, as it is the claims that must be relied upon in the earlier patent to show double patenting.

Otherwise, a patent could never issue as a continuation or division of an earlier patent without the filing of a terminal disclaimer in each and every continuation and divisional.

In view of the above remarks, the Examiner is respectfully requested to reconsider and withdraw the rejection of claims 2, 11, 17, 19, 43 and 71-92 on the ground of nonstatutory obviousness-type double patenting, as being unpatentable over the claims of U.S. Patent Numbers 5868763, 6190397 and 6565581, for failing to set forth a prima facie case of obviousness.

Conclusion

Applicants submit that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-2653, order number GUID-101CON4.

Respectfully submitted,

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